

SENATE BILL 306

By Miller

AN ACT to amend Tennessee Code Annotated, Title 33;
Title 49 and Title 68, relative to approval of clinical
trials at certain state institutions.

BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF TENNESSEE:

SECTION 1. Tennessee Code Annotated, Title 49, Chapter 7, Part 1, is amended by
adding the following as a new section:

49-7-135.

(a) On and after January 1, 2005, an institutional review board at a public
institution of higher education in this state, including the University of Tennessee system
and the state university and community college system, shall not approve a clinical trial
involving pharmaceutical products unless:

(1) The trial is registered with the clinical trials website maintained by the
National Institutes of Health (www.ClinicalTrials.gov); and

(2) The results of the trial are public records that are made available to
physicians and the public.

(b) The higher education commission is authorized to promulgate rules and
regulations to implement the provisions of this section in accordance with the provisions
of title 4, chapter 5. The rules may provide appropriate protections of information that is
confidential under state or federal law.

SECTION 2. Tennessee Code Annotated, Title 68, Chapter 11, Part 2, is amended by
adding the following as a new section:

68-11-259.

(a) On and after January 1, 2005, an institutional review board at a state-operated hospital licensed under this chapter or under title 33 shall not approve a clinical trial involving pharmaceutical products unless:

(1) The trial is registered with the clinical trials website maintained by the National Institutes of Health (www.ClinicalTrials.gov); and

(2) The results of the trial are public records that are made available to physicians and the public.

(b) The commissioner of health is authorized to promulgate rules and regulations to implement the provisions of this section in accordance with the provisions of title 4, chapter 5. The rules may provide appropriate protections of information that is confidential under state or federal law.

SECTION 3. This act shall take effect July 1, 2005, the public welfare requiring it.